REMARKS

This Amendment is responsive to the Office Action dated September 30, 2008. Applicant has amended claims 3, 11, 14, and 22 to correct formality issues unrelated to patentability. In addition, Applicant has added claims 23 and 24. Claims 1–24 are pending.

Summary of Examiner Interview

In telephonic interviews initiated by Applicant's representative, Jessica H. Kwak, on December 18, 2008, Applicant's attorney of record, Jessica H. Kwak, and Examiner Gedeon discussed the present application. The parties generally discussed independent claim 1 and U.S. Patent No. 6,317,633 to Jorgenson et al. (hereinafter referred to as "Jorgenson"), which was applied against Applicant's claim 1 in the Office Action dated September 30, 2008. Examiner Gedeon and Applicant's representative appeared to agree that Jorgenson failed to disclose or suggest increasing a safety factor used in setting a pacing pulse output energy, as required by Applicant's claim 1.

No exhibits were introduced during the interview, and no agreement was reached with respect to the claims. Applicant thanks Examiner Gedeon for taking the time to discuss the present application with Applicant's representative.

Claim Rejection Under 35 U.S.C. § 102(b)

In the Office Action, claims 1, 6, 11, 12, 16, 21, and 22 were rejected under 35 U.S.C. § 102(b) as being anticipated by Jorgenson Applicant respectfully traverses the rejection. Jorgenson fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

In support of the rejection of claim 1, the Office Action characterized lead impedance as an indicator of a likely increase in threshold required to effectively capture the heart.[1] According to the Office Action, Jorgenson discloses that a lead impedance test is done in the absence of a pacing threshold search that comprises delivering pacing pulses.[2] In addition, the Office Action

[1] Office Action at p. 3.
[2] *Id.*

reasoned that because Jorgenson discloses that "it is well known to apply a safety margin between the delivered pacing pulse and the stimulation threshold in order to ensure capture occurs," Jorgenson discloses each and every element of Applicant's claim 1. Applicant respectfully disagrees that Jorgenson discloses each and every element of claim 1.

Independent claim 1 is directed toward a method that comprises monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold search that comprises delivering pacing pulses, and increasing a safety factor used in setting a pacing pulse output energy if an indicator of increased pacing threshold is detected. Contrary to the Office Action's assertions, Jorgenson fails to disclose or suggest increasing a safety margin. As acknowledged by the Office Action, Jorgenson merely discloses that a safety margin between the delivered pacing pulse and the stimulation threshold may be applied. Application of a safety margin in no way suggests increasing a safety factor if an indicator of an increased pacing threshold is detected.

In addition to failing to disclose increasing a safety factor used in setting a pacing pulse output energy, Jorgenson fails to disclose or suggest increasing a safety factor if an indicator of an increased pacing threshold is detected, as required by claim 1. Jorgenson merely discloses determining a pacing threshold based on a pacing threshold search (which includes delivering pacing pulses), and increasing a pacing pulse width an amplitude from the threshold values to provide a safety margin to assure capture of the heart.[3] Thus, even if Jorgenson discloses that an increased lead impedance may result in loss of capture,[4] as noted by the Office Action, Jorgenson fails to disclose increasing the pacing values if the increased lead impedance is detected. Rather, Jorgenson appears only to increase the pacing pulse width and amplitude if a pacing threshold test indicates the pacing threshold has changed.[5]

Moreover, in Jorgenson reference, the pacing pulse width and amplitude appear to be adjusted independently of the detection of any indicator of a likely increase in pacing threshold in the absence of a pacing threshold search. For example, Jorgenson discloses that the pacing thresholds may be tested periodically, such as every night at a certain time.[6] Jorgenson fails to

[3] Jorgenson at col. 3, ll. 24–32.
[4] *Id.* at col. 3, ll. 12–17.
[5] *Id.* at col. 3, ll. 17–32.
[6] *Id.* at col. 13, ll. 24 and 29–33, and col. 13, ll. 29–32.

disclose or suggest that the pacing threshold is tested upon detecting an increased lead impedance.

Claim 1 recites automatically increasing a safety factor in the absence of the pacing threshold search. As discussed in Applicant's disclosure, it may be desirable to increase a safety factor used in setting a pacing pulse output energy in the absence of the pacing threshold search because there may be situations in which a rise in pacing threshold may not be detected by a pacing threshold search.[7] Jorgenson, on the other hand, does not disclose that a pacing threshold test may not be desirable if an indicator of a likely increase in pacing threshold is detected in the absence of a pacing threshold search that comprises delivering pacing pulses.

Independent claim 11 is directed to an implantable medical device (IMD) that includes a microprocessor that controls a pulse generator, receives sensed data from at least one electrode, and increases a safety factor used for setting the pacing pulse energy delivered by the pulse generator when an indicator of increased pacing threshold is detected. According to claim 11 as amended, the sensed data includes an indicator of increased pacing threshold and the sensed data is generated in the absence of a pacing threshold search that comprises delivery of the pacing pulses.

Independent claim 12 is directed to an IMD that comprises means for monitoring for indicators of a likely increase in pacing threshold in the absence of a pacing threshold search that comprises delivering pacing pulses and means for increasing a safety factor used in setting a pacing pulse output energy if an indicator of increased pacing threshold is detected.

Independent claim 22 is directed to an IMD that comprises, among other things, a microprocessor that controls a pulse generator, receives sensed data from at least one electrode, where the sensed data includes an indicator of increased pacing threshold, the indicator being associated with a compromised ability of the microprocessor to perform a pacing threshold search that comprises delivery of the pacing pulses, and increases a safety factor used for setting the pacing pulse energy delivered by the pulse generator when the indicator of increased pacing threshold is detected.

[7] Applicant's disclosure at paragraph [0010].

Jorgenson fails to disclose each and every limitation set forth in independent claims 1, 11, 12, and 22. Claims 6, 16, and 21 depend from claims 1, 12, and 11, respectively, and, therefore, Jorgenson also fails to disclose each and every element of dependent claims 6, 16, and 21. For at least these reasons, the Examiner has failed to establish a *prima facie* case for anticipation of Applicant's claims 1, 6, 11, 12, 16, 2,1 and 22 under 35 U.S.C. § 102(b). Reconsideration and withdrawal of the rejection of claims 1, 6, 11, 12, 16, 21, and 22 is respectfully requested.

Claim Rejection Under 35 U.S.C. § 103(a)

In the Office Action, claims 2–5 and 13–15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jorgenson in view of Lu (U.S. Patent No. 6,687,545). In addition, claims 7–10 and 17–20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Jorgenson in view of Ferek-Petric (U.S. Patent No. 7,317,943). Applicant respectfully traverses the rejection of the claims under 35 U.S.C. § 103(a).

Ferek-Petric Disqualification Under 35 U.S.C. § 103(c)

Applicant notes that Ferek-Petric is disqualified under 35 U.S.C. § 103(c) from being used in a rejection under 35 U.S.C. § 103(a) against the claims of the present application. Specifically, Ferek-Petric qualifies as prior art to the present application only under section 35 U.S.C. § 102(e). Applicant submits that, at the time the presently claimed invention was made, Ferek-Petric and the claimed invention were commonly owned, or subject to an obligation of assignment to the same person.

For at least this reason, Applicant respectfully requests withdrawal of the rejection of claims 7–10 and 17–20 under 35 U.S.C. § 103(a) as being unpatentable over Jorgenson in view of Ferek-Petric.

Jorgenson in view of Lu

Jorgenson in view of Lu fails to disclose or suggest each and every element of Applicant's claims 2–5 and 13–15. As discussed above, Jorgenson fails to disclose or suggest increasing a safety factor used for setting the pacing pulse energy delivered by the pulse generator when an indicator of increased pacing threshold is detected, as required by claims 1

and 12, from which claims 2–5 and 13–15 depend. Lu fails to cure this fundamental deficiency in Jorgenson. In addition, Lu fails to disclose or suggest the features of claims 2–5 and 13–15, as asserted by the Office Action. Applicant addresses some of the claims below for purposes of illustration.

Claim 2 specifies that the method of claim 1 further includes setting a time interval during which the increased safety factor is maintained and restoring the safety factor to a programmed value after the time interval has expired. In support of the rejection of claim 2, the Office Action asserted that Lu discloses a system that tests to detect a change in capture, and upon expiration of a timer, a system determines if an enhanced stimulation signal containing a safety margin is still necessary to ensure capture.[8] Applicant respectfully disagrees with the Office Action's characterization of Lu.

Lu discloses that a timer is reset each time a capture threshold test is performed.[9] Upon expiration of the timer, a threshold test for anodal stimulation is performed.[10] According to Lu, the anodal stimulation threshold is the lowest stimulation output at which anodal stimulation occurs.[11] Lu explicitly states that the anodal stimulation threshold should not be confused with the capture threshold required to depolarize the cardiac tissue.[12] Thus, the Office Action's assertion that Lu discloses that upon expiration of a timer, Lu discloses determining whether "an enhanced stimulation signal containing a safety margin is necessary to ensure capture"[13] was in error and finds no support within Lu. The only action that Lu appears to take after a time interval has expired is performing an anodal stimulation threshold test.[14] It is only if the anodal stimulation threshold has decreased that the Lu system determines whether the pacing output should even be modified.[15]

Moreover, Lu fails to disclose or suggest that the anodal stimulation threshold includes a safety factor, much less storing programmed safety factor values. Thus, Lu would not have

[8] Office Action at p. 4, item 6.
[9] Lu at col. 14, ll. 13–15.
[10] *Id.* at col. 14, ll. 23–33.
[11] *Id.* at col. 13, ll. 40–43.
[12] *Id.* at col. 13, ll. 40–43.
[13] Office Action at p. 4, item 6.
[14] Lu at col. 14, ll. 23–33.
[15] *Id.* at col. 14, ll. 34–40.

suggested the features of claim 2 to one having ordinary skill in the art, namely, restoring a safety factor to a programmed value after a time interval has expired, as required by claim 2.

It is unclear why one having ordinary skill in the art would have looked to Lu to modify Jorgenson. Jorgenson already proposes a solution to modifying a pacing threshold level. As discussed above, Jorgenson discloses that the pacing threshold test may be performed periodically, such as every night at a certain time.[16] Lu does not disclose the duration of its timer. Accordingly, neither Lu nor Jorgenson provide any basis for suggesting that the use of a timer to determine when a pacing threshold test is performed would have resulted in a more energy efficient system than the system disclosed by Jorgenson, as suggested by the Office Action.

Claim 3 discloses that the duration of the time interval is set according to the type of indicator of increased pacing threshold that has been detected. Neither Lu nor Jorgenson discloses or suggests the elements of claim 3. While Lu discloses a timer, Lu fails to provide any details regarding the duration of the timer or how it may be selected. Further, it is unclear why Lu would include more than one time interval or a time interval that is based on the detection of a specific indicator when Lu only discloses resetting a timer when one condition occurs (the performance of a capture verification test).[17] Accordingly, Jorgenson in view of Lu fails to disclose or suggest each and every element of claim 3.

Claim 5 discloses that the method of claim 1 further includes performing the pacing threshold search after detecting an indicator of increased pacing threshold, and reducing the increased safety factor back to a programmed value if the pacing threshold search yields a result. As discussed above, Jorgenson fails to disclose or suggest increasing a safety factor. Similarly, Lu fails to disclose or suggest increasing a safety factor. Thus, Jorgenson in view of Lu fail to disclose or suggest reducing an increased safety factor back to a programmed value, as required by claim 5.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 2–5, 7–10, 13–15, and 17–20 under 35 U.S.C. § 103(a). Reconsideration and withdrawal of this rejection is respectfully requested.

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[16] Jorgenson at col. 13, ll. 29–33.
[17] Lu at col. 14, ll. 13–15.

New Claims

Applicant has added claims 23 and 24 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. No new matter has been added by the new claims.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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